

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

UNITED STATES OF AMERICA, *et al. ex rel.*
CHARLES ARNSTEIN, *et al.*,

Plaintiffs,

- against -

TEVA PHARMACEUTICALS USA, INC., *et al.*,

Defendants.

13 Civ. 3702 (CM)

**SUPPLEMENTAL STATEMENT OF INTEREST OF
THE UNITED STATES OF AMERICA**

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Pursuant to 28 U.S.C. § 517, the United States of America (the “United States” or “government”) respectfully submits this supplement to its previously filed Statement of Interest, ECF No. 138-1 (“Gov’t SOI”), to set forth its position regarding the materiality of violations of the Anti-Kickback Statute (“AKS”), and the showing required to establish materiality. As discussed further below, the AKS statute, post-*Escobar* case law (including recent Southern District of New York precedent), and public sources all firmly establish that AKS violations—which are felonies punishable by up to five years in prison, *see* 42 U.S.C. § 1320a-7b(b)—are material to the government. If the Court is nevertheless inclined to conclude that the Relators here have not sufficiently established materiality, the government believes that the Court can and should rule narrowly on the adequacy of the record in this particular case.

First, as discussed in the Gov’t SOI, courts have long recognized, including in decisions issued since the Supreme Court’s decision in *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016) (“*Escobar I*”), that violations of the AKS are material. *See* Gov’t SOI at 7. *Escobar I* did not reverse the core principle, reflected in numerous district court decisions,¹ that compliance with the AKS is a fundamental condition of payment under all federal health care programs. This centrality of AKS compliance to the government’s decision to pay claims is an important factor weighing in favor of finding materiality. At least one court in this district has held, relying on *Escobar I*, that it “ha[d] no trouble concluding that compliance

¹ *See, e.g., United States ex rel. Kester v. Novartis Pharm. Corp.*, 41 F. Supp. 3d 323, 330 (S.D.N.Y. 2014) (observing that “[c]ourts have long held” that “compliance with the AKS is a precondition to the payment of Medicare and Medicaid claims”); *United States ex rel. Westmoreland v. Amgen, Inc.*, 812 F. Supp. 2d 39, 54-55 (D. Mass. 2011) (citing cases); *United States ex rel. Barrett v. Columbia/HCA Healthcare Corp.*, 251 F. Supp. 2d 28, 33 (D.D.C. 2003); *United States ex rel. Pogue v. Diabetes Treatment Ctrs. of Am.*, 238 F. Supp. 2d 258, 263 (D.D.C. 2002); *United States ex rel. Thompson v. Columbia HCA/Healthcare Corp.*, 20 F. Supp. 2d 1017, 1047-48 (S.D. Tex. 1999).

with the AKS is a ‘material’ condition of payment.” *United States ex rel. Wood v. Allergan, Inc.*, 246 F. Supp. 3d 772, 818 (S.D.N.Y. 2017), *rev’d on other grounds*, *United States ex rel. Wood v. Allergan, Inc.*, 899 F.3d 163 (2d Cir. 2018). The district court in *Wood* explained that “violation of the AKS is a far cry from an ‘insubstantial’ regulatory violation . . . [i]ndeed, Congress has made it a felony offense punishable by up to five years in prison, and . . . the law now provides explicitly that ‘a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim.” *Id.* Furthermore, as noted in *Wood*, the continued materiality of AKS violations post-*Escobar I* is evidenced by the fact that Medicare Part D Provider Agreements and the majority of state Medicaid Provider Applications expressly designate AKS compliance as a condition of payment. *Id.* Other courts that have considered the materiality of AKS violations following *Escobar I* have similarly reached the conclusion that, absent any evidence of actual knowledge to the contrary (as discussed further below), AKS violations are material to the government’s decision to pay claims. *See, e.g., United States ex rel. O’Donnell v. Am. at Home Healthcare*, No. 14 Civ. 1098, 2017 WL 2653070, at * 9 (N.D. Ill. June 6, 2017); *U.S. ex rel. Lutz v. Berkeley HeartLab, Inc.*, No. 14-230, 2017 WL 4803911, at *7 (D.S.C. Oct. 23, 2017).²

² In contrast, none of the authorities that Teva relies upon in its response to the government’s statement of interest to support its view of materiality involve alleged AKS violations. *See United States ex rel Brown v. Pfizer, Inc.*, Civil Action No. 05-6795, 2017 WL 2691927, at *4 (E.D. Pa. June 22, 2017) (allegations regarding false information submitted to FDA); *Bishop v. Wells Fargo & Co.*, 823 F.3d 35, 44 (2d Cir. 2016) (allegations regarding false information submitted to Federal Reserve and federal home loan banks); *United States ex rel. Kolchinsky v. Moody’s Corp.*, 238 F. Supp. 3d 550, 558 (S.D.N.Y. 2017) (allegations regarding manipulation of credit ratings); *United States ex rel. Bachert v. Triple Canopy, Inc.*, 321 F. Supp. 3d 613, 620 (E.D. Va. June 8, 2018) (allegations regarding falsification of weapons inspection records); *United States ex rel. Berg v. Honeywell Int’l, Inc.*, 740 Fed. App’x 535 (9th Cir. 2018) (allegations regarding false statements with respect to savings and infiltration rates); *United States ex rel. Nargol v. DePuy Orthopedics, Inc.*, 865 F.3d 29 (1st Cir. 2017) (allegations regarding representations relating to FDA approval); *United States ex rel. Petratos v. Genentech*

Moreover, as the government’s previously filed Statement of Interest also explained, the simple fact that a federal healthcare program continues to pay claims after learning of AKS violations is not evidence that those violations are immaterial. *See* Gov’t SOI at 9-13. There are a variety of circumstances in which the government might elect to keep paying claims, for example to innocent beneficiaries or other third parties, while still considering AKS violations to be material. *Id.* Furthermore, the Supreme Court itself has distinguished between the potential probative value of the government’s “actual knowledge” of AKS violations and mere awareness of alleged violations. *See Escobar I*, 36 S. Ct. at 2003. *see also United States ex rel. Escobar v. Universal Health Servs., Inc.*, 842 F.3d 103, 112 (1st Cir. 2016) (“*Escobar II*”) (“mere awareness of allegations concerning noncompliance with regulations is different from knowledge of actual noncompliance”). Teva has not asserted here that the government had actual knowledge of any AKS violations. The mere fact that the government continued to pay claims after *qui tam* allegations were filed would not compel the conclusion in this case that the AKS violations were immaterial.

To the extent the Court holds that an additional evidentiary showing supporting materiality is required, publicly available materials demonstrate that AKS violations are material to the government. As early as 2003, the Department of Health and Human Services, Office of Inspector General (“HHS OIG”) issued guidance to pharmaceutical manufacturers advising them

Inc., 855 F.3d 481, 490 (3d Cir. 2017) (allegations regarding representations made to FDA for approval); *United States ex rel. McBride v. Halliburton Co.*, 848 F.3d 1027, 1034 (D.C. Cir. 2017) (allegations regarding inflated headcount data); *United States ex rel. Harman v. Trinity Indus., Inc.*, 872 F.3d 645 (5th Cir. 2017) (allegations regarding misrepresentation of design for guardrail end terminals); *United States ex rel. Marshall v. Woodward.*, 812 F.3d 556 (7th Cir. 2015) (allegations regarding non-conforming replacement helicopter parts); *City of Chicago v. Purdue Pharma L.P.*, 211 F. Supp. 3d 1058 (N.D. Ill. 2016) (allegations regarding false marketing information and failure to identify risks of opioids).

to “be aware of the federal anti-kickback statute and the constraints it places on the marketing and promotion of products reimbursable by the federal health care programs, including, but not limited to, Medicare and Medicaid.” Dept. of Health and Human Servs., Office of Inspector Gen., Compliance Program Guidance for Pharmaceutical Manufacturers, (“2003 Pharma Guidance”), 68 Fed. Reg. 23, 731 (May 5, 2003). The 2003 Pharma Guidance also made clear to companies like Teva that HHS-OIG viewed AKS violations as grounds for “exclusion from the federal health care programs,” as well as for “liability under the False Claims Act.” *Id.* at 23734. In addition to emphasizing the importance of AKS compliance generally, the 2003 Pharma Guidance went further to specifically identify as a “Key Area[] of Potential Risk” kickback payments made in the form of “Educational Grants” to medical speakers. *Id.* at 23733-23735. The 2003 Pharma Guidance, as well as other documents that reflect HHS-OIG’s significant and comprehensive efforts to enforce the AKS administratively, civilly, and criminally,³ all evidence

³See e.g., HHS-OIG, *Semiannual Reports to Congress*, <https://oig.hhs.gov/reports-and-publications/semiannual/index.asp> (reviewing enforcement actions taken against AKS violators); HHS-OIG, *Special Fraud Alerts*, <https://oig.hhs.gov/compliance/alerts/index.asp> (providing industry and law enforcement alerts as to fraud activity, including AKS violations); and HHS-OIG, *Compliance Guidance*, <https://oig.hhs.gov/compliance/compliance-guidance/index.asp> (providing guidance to various healthcare providers, including as regards to AKS compliance).

The referenced HHS-OIG documents are public records of “a public office” that “set[] out the office’s activities” and, therefore, are admissible under Rule 803(8) of the Federal Rules of Evidence. See *In re MBTE Prods. Liab. Litig.*, 591 F. Supp. 2d 259, 277 n. 83 (S.D.N.Y. 2008). Moreover, as numerous courts in this Circuit have recognized, admissible evidence from public records can create genuine disputes of fact for purposes of summary judgment. See, e.g., *Goldstein v. Laurent*, No. 09 Civ. 2437 (PKC), 2011 WL 3586447, at *4 (S.D.N.Y. Aug. 2, 2011) (statement from police report, which is admissible as a public record, “is sufficient admissible evidence to create a genuine issue for trial”); *Siuzdak v. Sessions*, 295 F. Supp. 3d 77, 106 (D. Conn. 2018) (denying summary judgment based on corrective action order admitted pursuant to Rule 803(8)); *Jo v. JPMC Specialty Mortg., LLC*, 135 F. Supp. 3d 54, 68 n. 9 (W.D.N.Y. 2015) (evidence admissible pursuant to Rule 803(8) sufficient to create a dispute of fact).

the materiality of AKS compliance to the government. Indeed, the government frequently pursues False Claims Act prosecutions and criminal proceedings to deter and punish AKS violations. *See, e.g., U.S. ex rel. Bilotta v. Novartis Pharm. Corp.*, 50 F. Supp. 3d 497 (S.D.N.Y. 2014).⁴

Notwithstanding these publicly available sources and the government's other arguments set forth herein, if the Court remains skeptical of Relator's showing regarding materiality here, the government believes that it would be not only possible but also most prudent to limit the Court's ruling to the scope of the record in this particular case, which does not reflect any evidence directly from the government or any government witness regarding the materiality of the AKS violations in this case, if they are proven. As the payor of claims that may be tainted by AKS violations, evidence obtained from the government on the issue of materiality would certainly be probative. In the absence of any such evidence reflected in the record here, the Court need not issue a broad rule formulating an evidentiary standard for materiality in every AKS case.

⁴ The government's decision not to intervene in this particular matter likewise has no bearing on the materiality inquiry. Courts have repeatedly recognized that the government "may have a host of reasons for not pursuing a claim," and courts should "not assume that in each instance in which the government declines intervention in an FCA case, it does so because it considers the evidence of wrongdoing insufficient or the qui tam relator's allegations [of] fraud to be without merit." *United States ex rel. Atkins v. McInteer*, 470 F.3d 1350, 1360 n.17 (11th Cir. 2006); *see also United States ex rel. Chandler v. Cook County, Ill.*, 277 F.3d 969, 974 n.5 (7th Cir. 2002), *aff'd*, 538 U.S. 119 (2003); *United States ex rel. Berge v. Bd. of Trs. of the Univ. of Ala.*, 104 F.3d 1453, 1458 (4th Cir. 1997).

Respectfully submitted,

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